SECTION 8-510(K) SUMMARY

K021261

510(k) Summary

Galil Medical - SeedNet™ System

510(k) Number

Company Name:

Galil Medical Ltd.

Contact Person:

Dr. Roni Zvuloni,
Director of IP & Regulatory Affairs
Telephone: +972-4-959 10 80
Fax: +972-4-959 10 77

Trade Proprietary Name:

SeedNet™ System , SeedNetGold™ System

Classification Name:

CRYOSURGICAL UNIT

Classification:

GEH

Predicate Devices:

1. SeedNet™
2. CRYO-HIT™

Indication for Use:

The modified SeedNet is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

The modified SeedNet has the following specific indications:

Urology (ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia "BPH")

Oncology (ablation of cancerous or malignant tissue and benign tumors, and palliative intervention)

Dermatology (ablation or freezing of skin cancers and other cutaneous disorders. Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas small hemanglomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratoses, cavernous hemanglomas, perianal condylomata, and palliation of tumors of the skin)

Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia)

General surgery (palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions.)

*ENT (*Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth).

Thoracic surgery (ablation of arrhythmic cardiac tissue cancerous lesions)

Proctology (ablation of benign or malignant growths of the anus or rectum, and hemorrhoids)

The Modified SeedNet System may be used with a magnetic resonance imaging (MRI) device or an ultrasound device to provide real-time visualization of the cryosurgical procedure.

Technological Characteristics:

The Galil Medical's SeedNet™ System is a modification of Galil Medical LTD's cleared SeedNet™ System (K011950). The SeedNet™ System is the exact same device as the SeedNet™ except for the following modifications to its technological characteristics:

1. The inclusion of cryoanalgesia as an example of the device's cleared neurology general indication.
2. The addition of a 4.5 mm surface probe.
3. Addition of trade name: SeedNetGold™ System.
4. Provision of the use of the modified SeedNet system together with magnetic resonance imaging (MRI) device.

Substantial Equivalence

The modified SeedNet has the same intended use as the cleared SeedNet™ and the Cryo-Hit™, the same general and specific indications as the Cryo-Hit™, the same general and specific indications as the cleared SeedNet, except for the provision of the cryoanalgesia example of a neurology indication, the same principles of operation as the cleared SeedNet™ and the Cryo-Hit™, and the same technological characteristics as a combination of the cleared Cryo-Hit and the cleared SeedNet™ . The inclusion of the cryoanalgesia as an example of the device's cleared neurology general indication, the addition of the Cryo-Hit's cleared 4.5 mm surface probe, and the MRI option do not raise any question of safety and effectiveness. The use of the alternative SeedNet Gold™ System trade name does not affect the safety or effectiveness of the device. Thus, the modified SeedNet System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2002

Galil Medical LTD.
c/o Jonathan S. Kahan
Hogan & Hartson
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Re: K021261
Trade Name: SeedNet™ System (SeedNet Gold™ System)
Regulation Number: 878.4350
Regulation Name: Cryosurgical unit
Regulatory Class: Class II
Product Code: GEH
Dated: April 17, 2002
Received: April 19, 2002

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K021261

Device Name: SeedNet™ System (SeedNet Gold™ System)

Indications for Use:

The SeedNet™ System (SeedNet Gold™ System) is intended for cryogenic destruction of tissue during surgical procedures.

It is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

The SeedNet™ System (SeedNet Gold™ System) has the following specific indications:

Urology (ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia "BPH")

Oncology (ablation of cancerous or malignant tissue and benign tumors and palliative intervention)

Dermatology (ablation or freezing of skin cancers and other cutaneous disorders. Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of

the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas small hemanglomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratoses, cavernous hemanglomas, perianal condylomata, and palliation of tumors of the skin)

Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia)

General surgery (palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions.)

ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth).

Thoracic surgery (ablation of arrhythmic cardiac tissue and cancerous lesions,)

Proctology (ablation of benign or malignant growths of the anus or rectum and hemorrhoids)

The SeedNet™ System (SeedNet Gold™ System) may be used with a magnetic resonance imaging (MRI) device or an ultrasound device to provide real-time visualization of the cryosurgical procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

510(k) Number

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021261

Prescription Use ___X___ OR Over the Counter Use_____
(Per 21 CFR 801.109)